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October 7, 2003

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Robert E. Hanson

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: SN 09/818,921 "FERTILE TRANSGENIC CORN PLANTS" – Ronald C. Lundquist, et al.;
Our Ref.. DEKM:047USD5; Client Ref. 51209 US 25

Commissioner:

Enclosed for filing in the above-referenced patent application is:

1. An Appeal Brief (an original and two copies);

2. A check in the amount of $330.00 in payment of the required filing fee; and

3. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

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Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ronald C. Lundquist *et al.*

Serial No.: 09/818,921

Filed: March 27, 2001

For: FERTILE TRANSGENIC CORN PLANTS

Group Art Unit: 1638

Examiner: Ann R. Kubelik

Atty. Dkt. No.: DEKM:047USD5

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October 7, 2003
Date

Robert E. Hanson

BRIEF ON APPEAL

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ronald C. Lundquist *et al.*	Group Art Unit: 1638
Serial No.: 09/818,921	Examiner: Gary Benzion
Filed: March 27, 2001	Atty. Dkt. No.: DEKM:047USD5
For: FERTILE TRANSGENIC CORN PLANTS	

BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief in response to the Final Office Action dated June 17, 2003. The fee for filing this Appeal Brief is attached hereto. This Brief is filed pursuant to the Notice of Appeal mailed August 4, 2003. The date for filing the instant Brief is October 7, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on August 7, 2003. No additional fees are believed due in connection with the instant paper. However, should any other fees be due, or the attached fee be deficient or absent, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKM:047USD5/RH10056. Please date stamp and return the enclosed postcard to evidence receipt of this document.

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I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent company of assignee DEKALB Genetics Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no interferences or appeals for related cases.

III. STATUS OF THE CLAIMS

Claims 1-9 were filed with the original specification. Claims 10-32 were added and claims 1-9 deleted in a Preliminary Amendment filed concurrently with the instant application on March 27, 2001. Claims 10-32 were pending at the time of the final Office Action and are currently pending in the case. The final rejection of claims 10-32 is the subject of the instant appeal. A copy of the appealed claims is attached hereto as Appendix 1.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to a process for producing a fertile transgenic *Zea mays* plant which possesses heritable recombinant DNA that encodes a *Bacillus thuringiensis* (Bt) endotoxin, wherein the DNA is adjusted to be expressed efficiently in *Zea mays* so as to impart insect resistance. Specification at page 7, lines 15-19. The DNA may adjusted so that it comprises an increased number of maize preferred codons. Specification at page 18, lines 16-31. The DNA

may also comprise a truncated *Bacillus thuringiensis* (Bt) endotoxin. Specification at page 20, lines 28-31

VI. ISSUE ON APPEAL

A. Are claims 10-32 obvious under 35 USC § 103(a) over Tomes *et al.* in view of each of Barton *et al.*, Vaeck *et al.* and Adang *et al.*?

B. Is claim 25 obvious under 35 U.S.C. 103(a) over Tomes *et al.* in view of each of Barton *et al.*, Vaeck *et al.* and Adang *et al.*, as applied to claims 10-24, 26-27, and 29-32 in further view of Adang *et al.*?

C. Are claims 10-15, 18-24, 27, 29 and 31-32 obvious under 35 U.S.C. 103(a) over each of Klein *et al.* (1989), Klein *et al.* (1988a), Klein *et al.* (1988b) and Sanford *et al.* in view of Shillito *et al.*?

VII. GROUPING OF THE CLAIMS

The claims stand or fall together.

VIII. SUMMARY OF THE ARGUMENT

The Examiner initially rejects claims 10-24, 26-27, and 29-32 under 35 USC § 103(a) over Tomes *et al.* in view of Barton *et al.*, Vaeck *et al.* and Adang *et al.* It is alleged that Tomes *et al.* teaches creation of transgenic maize, but not maize transformed with a nucleic acid encoding a Bt endotoxin wherein the nucleic acid is adjusted to be more efficiently expressed in maize, but that Barton *et al.* and Vaeck *et al.* teach tobacco plants transformed with a vector encoding a truncated *Bacillus thuringiensis* (Bt). The Examiner thus alleges that it would have been obvious to create transgenic maize expressing a modified Bt. The rejection fails because

the Examiner has impermissibly used hindsight reconstruction and has not shown a teaching of all elements of the claims in the prior art. The Examiner applied references concerning transgenic tobacco to the claims, without any basis to support the relevancy to the claims, which concern transgenic maize. Appellants have further affirmatively submitted numerous lines of evidence to show that these references have no relevance to the claims. The Examiner's conclusion are therefore completely without scientific or legal support and the rejections thus violates the standards of the APA. The Examiner has further ignored the fact that the claims require production of insect resistant plants, which has not even alleged been alleged to be found in the prior art. The rejection therefore must be reversed.

The Examiner finally rejected claim 25 under 35 U.S.C. § 103(a), as applied to claims 10-24, 26-27 and 29-32, over Tomes *et al.* in view of each of Barton *et al.*, Vaeck *et al.* and Adang *et al.*, in further view of Adang *et al.* (U.S. 5,380,831, 1988). It was stated that Adang *et al.* (1988) teach a method of codon optimization of Bt endotoxin genes, wherein the method is applied to optimization for expression in monocots such as maize, and that it would have been obvious to modify the method of transformation of maize to use a nucleic acid encoding a *Bt* endotoxin. The rejection is substantively identical to the base rejection with the exception of Adang *et al.* (1988). However, the addition of the reference cures none of the defects of the base rejection. Adang is entirely prophetic with regard to transgenic monocot plants and insect resistance. No basis has been provided to indicate why insect resistance could be achieved at all in *Zea mays*. In essence, the position of the Examiner is that because a codon-preferred sequence was made, it must work. However, the only basis for this conclusion is found in Appellants disclosure. Impermissible hindsight reconstruction has thus been used and the rejection must be reversed.

The Examiner finally rejected 10-15, 18-24, 27, 29 and 31-32 under 35 U.S.C. § 103(a) as being unpatentable over each of Klein *et al.* (1989), Klein *et al.* (1988a), Klein *et al.* (1988b) and Sanford *et al.*, in view of Shillito *et al.* The rejection initially fails because it does not even cite a method that can be alleged to transform *Zea mays*. The claims of Shillito are cited for this element, but are silent on transformation. The Examiner has also used hindsight reconstruction to allege that Shillito "teach expression of truncated genes in maize plants" simply because a truncated Bt is mentioned. The allegations were made without support and in violation of the APA. None of the references are alleged to teach any insecticidal activity in plant cells, let alone teach transgenic *Zea mays* plants in general. This element is missing from the cited art and the rejection must be reversed.

VIII. ARGUMENT

A. Claims 10-32 were improperly rejected under 35 USC § 103(a) over Tomes *et al.* in view of each of Barton *et al.*, Vaeck *et al.* and Adang *et al.*

The Examiner has finally rejected appealed claims 10-24, 26-27, and 29-32 under 35 USC § 103(a) over Tomes *et al.* (U.S. 5,886,244, filed June, 1988) in view of each of Barton *et al.* (1987, *Plant Physiol.* 85:1103-1109), Vaeck *et al.* (1987, *Nature* 328:33-37) and Adang *et al.* (1985, EP 142,924). It is stated that Tomes *et al.* teaches creation of transgenic maize, but not a method of transformation of maize by microprojectile bombardment with a nucleic acid encoding a Bt endotoxin, wherein the nucleic acid is adjusted to be more efficiently expressed in maize. The Action states that Barton *et al.* and Vaeck *et al.* teach tobacco plants transformed with a vector encoding a truncated *Bacillus thuringiensis* (Bt). The Examiner alleges that it would have been obvious to one of ordinary skill in the art to modify the method of

transformation of maize taught by Tomes *et al.* to transform maize with nucleic acids encoding the truncated HD-1 or HD-73 Bt as described in each of Barton *et al.* and Adang *et al.* (1985) or fused in frame with a selectable marker or reporter gene as described in Vaeck *et al.*

The Examiner has failed to provide any support for the conclusions drawn. Rather, the Examiner cites the references discussing expression of truncated Bt in tobacco and concludes, without any basis or reasoning, that "[b]ecause the endotoxin gene is truncated, it would be more efficiently expressed in maize." This conclusion is completely without support, and as is described further below, is made in violation of the standards of the APA.

1. The Examiner has failed to show the relevance of the cited prior art to the claimed invention

Even if it is assumed, *arguendo*, that the references cited by the Examiner show expression of truncated Bt in tobacco, the Examiner has failed to provide any basis to indicate why this would be relevant to the claims, which concern *Zea mays* (e.g., corn). The rejection is therefore unsupported and has been made using an impermissible "obvious to try" rationale. Further, the reasoning of the Examiner is scientifically incorrect.

Tobacco and corn are distantly related: tobacco is a dicotyledonous (dicot) plant and corn a monocotyledonous (monocot) plant. As the Federal Circuit noted in *PGS v. DeKalb*, flowering plants can be broadly categorized as either monocots and dicots, depending on whether the initial development of the seed produces one leaf (monocot) or two leaves (dicot). 315 F.3d 1335, 1338 (Fed. Cir. 2003). In *PGS v. DeKalb*, the Federal Circuit upheld a district court ruling that the patent of plaintiff PGS was invalid for lack of enablement because the claims read on both monocot and dicot cells with a herbicide tolerance gene, but that only dicots were enabled. 315 F.3d at 1346. All of the working example in PGS' patent were dicots, such as tobacco, tomato

and potato. PGS claims were found invalid for lack of enablement, because as of the 1987 priority date of PGS' patent the scientific community was unable to transform monocots, although it could transform dicots. The phenomenon was described as a "monocot barrier." *PGS v. DeKalb*, 175 F. Supp. 2d 246, 261 (D. Conn., 2001). The district court further noted that transformation of corn was not reported until 1990, by Dekalb Genetics Corporation, the assignee of the current case. The court cited an August 10, 1990 article published in *Science*, which announced DeKalb's success as "the capstone of almost a decade's efforts to genetically engineer this country's most important crop." Id. at 263-264, citing A. Moffat, *Corn Transformed*, 249 Science 630 (1990). This article noted that in the summer of 1990, microprojectile technology "appeared to be the only satisfactory technique for transforming whole cells of monocots and these transformed cells are amenable to cell culture." *Id.* The Examiner's statements regarding the presumption of validity of Tomes aside, the foregoing demonstrates that, as of the filing date of the instant application, there was a very low level of skill in the art. It is respectfully submitted that the Examiner has failed to take this into account by applying hindsight reconstruction.

The information above demonstrates, at a minimum, that tobacco and corn do not behave the same for purposes of genetic manipulation. The Examiner's conclusory statement's to the contrary are simply unsupported. The priority date of at least April 11, 1990 for this application underscores this. The Examiner has provided no basis to indicate why the cited work in tobacco has any relevance to the instant claims. The Examiner has failed to meet any of the requirements to maintain a rejection under §103; namely there has been no showing of a motivation to combine the cited references, showing of all elements of the claims, or demonstration of a reasonable expectation of success.

The foregoing is also demonstrated by another Federal Circuit opinion. In *Adang v. Fischhoff*, the Federal Circuit considered whether a patent application disclosing transgenic tobacco plants encoding Bt and exhibiting toxicity to Lepidopterans was enabling for insecticidal tomatoes expressing a full length Bt when combined with contemporaneous publications and a citation in the application to a method for transforming tomatoes. 286 F.3d 1346, 1350 (Fed. Cir. 2002). The application at issue was apparently a CIP of the U.S. application that corresponds to the Adang European counterpart application (EP 142 924) cited in the instant rejection. *Id.* at 1349.

Citing evidence submitted by the patent owner showing that bioassays could vary even among different strains of tobacco, the Federal Circuit found evidence of non-enablement in the findings of the Board of Patent Appeals and Interferences, holding these to have been supported by substantial evidence. *Id* at 1360. The Federal Circuit cited the conclusion of the Board that:

> persons skilled in the art ***would not have expected success*** in regenerating tomato plants insecticidal to Lepidopteran insects from dicotyledonous tomato plant cells transformed by a full length Bt crystal protein gene based on evidence that tobacco cells had been ***successfully transformed*** by the same genetic construct and one strain of dicotyledonous tobacco plants insecticidal to Lepidopteran insects had been regenerated therefrom. (emphasis added) (*Id.* at 1350)

The court therefore found a lack of enablement. Evidence regarding the unpredictability of expressing Bt genes and foreign genes in general in plants was considered in the decision. Specifically cited was the evidence that gene expression in one strain of tobacco is not necessarily predictive even of expression in other strains of tobacco, let alone other plants such as tomato. *Id.* at 1356. The court therefore found it "reasonable to conclude that those of skill in the art would not have expected expression in tomato plants to track that in a particular strain of tobacco." *Id.* Contemporaneous references discussing expression of Bt in tobacco, including the very Adang, Barton and Vaeck references cited here, were not found to cure any defects in

enablement. *Id* at 1357-58. The court further held that citation to a general method for transformation of tomato did not remedy the deficiencies of the Adang patent application, given the unpredictable nature of the claimed subject matter. *Id.* at 1358.

The Examiner attempts to downplay this evidence by stating that the issue involved concerned expression of full length Bt. However, this ignores the real issue, which is that the Examiner is attempting to employ the same flawed reasoning that was rejected by the Federal Circuit in *Fischoff.* The Examiner is extrapolating data from tobacco to maize without any support. The Federal Circuit in *Fischoff* suggested that expression of full length Bt may not be predictable ***even among strains of tobacco***. Regardless of whether discussing full length or truncated Bt, *Fischoff* demonstrates that the conclusions of the Examiner have been impermissibly made. In *Fischoff*, the plants being compared were tomato and tobacco, which are both dicots. The Examiner's attempt to apply results from tobacco in maize are an even bigger leap and cannot stand in view of *Fischoff.*

2. The Examiner has failed to support the rejection in violation of the APA

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are completely unsupported in fact or law. At a

minimum, the Examiner must support the basis for a rejection. The Examiner has instead made conclusory statements regarding the motivations and expectations of one of skill in the art. Such statements must be supported on the record to comply with the standards of the APA. The Examiner has failed to do this and therefore the rejection must be reversed.

3. None of the cited references describe a fertile transgenic corn plant and thus one of skill in the art was without an expectation of success in expressing any given transgene

Appellants next note that ***none*** of the cited references describe a ***fertile transgenic corn plant***. Tomes is cited as teaching such a plant based on what it claims, but a review of the specification demonstrates that ***Tomes is entirely prophetic*** with regard to fertile transgenic corn plants. This is further evidence of the shortcomings of the cited art. Given that the prior art fails to teach an actual fertile transgenic plant at all, there is simply no basis to indicate why one of skill in the art would have an expectation of expressing any given gene, let alone a modified Bt gene. The mere citation of a general transformation method would indicate nothing to one of skill in the art whether modified Bt can be expressed in maize. *Adang v. Fischhoff*, 286 F.3d 1346, 1358 (Fed. Cir. 2002). As described above, citation to transgenic tobacco does not cure this defect.

B. Claim 25 is not obvious under 35 U.S.C. 103(a) over Tomes *et al.* in view of each of Barton *et al.*, Vaeck *et al.* and Adang *et al.*, as applied to claims 10-24, 26-27, and 29-32 in further view of Adang *et al.*

The examiner has finally rejected appealed claim 25 under 35 U.S.C. 103(a), as applied to claims 10-24, 26-27 and 29-32, as being unpatentable over Tomes *et al.* (U.S. 5,886,244, filed June, 1988) in view of each of Barton *et al.* (1987, *Plant Physiol.* 85:1103-1109), Vaeck *et al.*

(1987, *Nature* 328:33-37) and Adang *et al.* (1985, EP142,924) in further view of Adang *et al.* (U.S. 5,380,831, filed September, 1988). In particular, it is stated that Adang *et al.* (1988) teach a method of codon optimization of Bt endotoxin genes, wherein the method is applied to optimization for expression in monocots like maize, and that, at the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of transformation of maize by microprojectile bombardment with a nucleic acid encoding a *Bt* endotoxin by the method of Tomes *et al.* in view of each of Barton *et al.* and Adang *et al.* (1985).

The rejection is substantively identical to the rejection of claims 10-24, 26-27, and 29-32 discussed above under 35 USC § 103(a), except that Adang *et al.* (U.S. 5,380,831, filed September, 1988) has been added and cited as teaching codon optimization. Appellants therefore herein incorporate by reference and re-urge the arguments above with respect to the instant rejection. The added reference cures none of the defects in the rejection of claims 10-24, 26-27, and 29-32. It has not been alleged that the reference teaches transgenic corn or the expression of Bt to achieve insect resistance. Adang is entirely prophetic with regard to transgenic monocot plants. As mentioned above, the Examiner has not even shown the existence of such a plant prior to the priority date of Appellants application. As mentioned in A. Moffat, *Corn Transformed*, 249 Science 630 (1990), there was not even a satisfactory technique for transforming whole cells of monocots amenable to cell culture until 1990, well after Adang's 1988 priority date.

In essence, the position of the Examiner is that because a codon-preferred sequence was made, it must work. However, the basis for this conclusion must come from the prior art, not Appellants disclosure. No reasoning is provided to indicate why this would work in maize. All elements of the claims are thus not found in the prior art and there would be no reasonable

expectation of success in arriving at the invention. Appellants thus request reversal of the rejection.

C. Claims 10-15, 18-24, 27, 29 and 31-32 are not obvious under 35 U.S.C. 103(a) over each of Klein *et al.* (1989), Klein *et al.* (1988a), Klein *et al.* (1988b) and Sanford *et al.* in view of Shillito *et al.*

The Examiner has finally rejected appealed claims 10-15, 18-24, 27, 29 and 31-32 under 35 U.S.C. 103(a) as being unpatentable over each of Klein *et al.* (1989, *Plant Physiol.* 91:440-444), Klein *et al.* (1988a, *Proc. Natl. Acad. Sci.* USA 85:4305-4309), Klein *et al.* (1988b, *Bio/Technol.* 6:559-563) and Sanford *et al.* (US Patent 5,036,006, filed June, 1986) in view of Shillito *et al.* (US Patent 5,350,689, filed November, 1988).

The cited references suffer from the same shortcomings as the references cited above and Appellants therefore herein incorporate the arguments made with respect to the previous rejections by reference herein. The rejection also contains additional defects, as described below.

1. No method for creation of fertile transgenic plants has been cited

The Action acknowledges that none of Klein *et al.* 1989, Klein *et al.* 1988a, Klein *et al.* 1988b and Sanford *et al.* disclose maize cells transformed with a modified Bt and regeneration of plants therefrom. It further has not been directly alleged that any of these references teach fertile transgenic plants. It is only stated that these references teach transformation of maize cells. Shillito is cited for this element.

With respect to Shillito, it is noted that the portion of the reference cited in the first Action as producing progeny from regenerated, transformed maize plants (Col. 21, lines 16-30) is entirely prophetic. No transgenic maize plants are described. Appellants respectfully submit

that this is because Shillito is not enabling and does not disclose any cell lines capable of being transformed and regenerated into fertile transgenic maize plants. Having pointed this out, the examiner cited claims 1 and 11 and relied upon the presumption of validity of patents. However, tellingly, the claims ***do not concern transgenic plants***. None of the steps in claims 1 or 11 involve ***transformation*** of the cells recited. For example, claim 1 of Shillito reads as follows:

> 1. A Zea mays protoplast or a protoplast-derived plant cell of Zea mays, wherein said protoplast or protoplast-derived cell is capable of regenerating fertile Zea mays plants, and wherein said protoplast or protoplast-derived cell is obtained by a process comprising the steps of:
> (a) obtaining embryogenic Zea mays callus that is relatively nonmucilaginous, and is granular and friable, said callus being obtained by culturing an immature Zea mays embryo on a callus-inducing medium comprising 2,4-D followed by the culture of said callus on a callus-maintaining medium comprising 2,4-D,
> (b) transferring the callus to a liquid medium to form a suspension of cells or cell aggregates,
> (c) subculturing the suspension under conditions sufficient to maintain the cells and cell aggregates in a viable state,
> (d) selecting and retaining those cultures from the subcultured suspension of step (c) that contain aggregates of dense, cytoplasmic, dividing cells, sufficient to obtain, in a viable, dividing stage, Zea mays protoplasts capable of being regenerated into fertile plants, and
> (e) removing the cell walls with suitable enzymes, and isolating Zea mays protoplasts.

As can be seen, there is no transformation of these cells. Claim 11 of Shillito reads as follows:

> 11. A method for producing cell suspension cultures of Zea mays cells and cell aggregates from which protoplasts can be isolated, wherein the protoplasts are capable of regenerating fertile plants, which method comprises the steps of:
> (a) obtaining embryogenic Zea mays callus that is relatively nonmucilaginous, and is granular and friable, said callus being obtained by culturing an immature Zea mays embryo on a callus-inducing medium comprising 2,4-D followed by the culture of said callus on a callus-maintaining medium comprising 2,4-D,
> (b) transferring the callus to a liquid medium comprising 2,4-D to form a suspension of cells or cell aggregates,
> (c) subculturing the suspension (i) for a period of time and (ii) with a frequency sufficient to maintain any cells and cell aggregates in a viable state,
> (d) selecting and retaining those cultures from the subcultured suspension of step (c) that contain aggregates of dense, cytoplasmic, dividing cells, sufficient to

obtain, in a viable, dividing stage, Zea mays protoplasts capable of being regenerated into fertile plants.

Once again, the claim does not involve transformation of cells. The Examiner has therefore failed to cite any method that can even be alleged to describe transformation of corn ***plants***. The rejection therefore cannot stand.

2. Hindsight reconstruction has been used by the Examiner

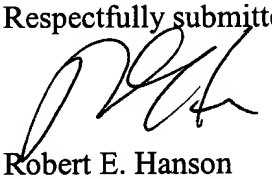
The Action has not alleged that any of the references other than Shillito teach fertile transgenic plants. Shillito is cited as teaching a truncated Bt. Based on Shillito's citation to truncated Bt, it is concluded that "Shillito teach expression of truncated genes in maize plants." Final Action, p7. Similarly, the first Action alleges that the vectors of Shillito would "more efficiently express the endotoxin in maize." First Action p6. However, these allegations have been made completely without support and in violation of the APA. This is classic hindsight reconstruction based on Appellants specification. The Examiner must support such conclusory allegations with the prior art, not based upon Appellants invention. None of the references are even alleged to teach any insecticidal activity in plant cells, let alone teach transgenic maize. This element is therefore missing from the cited art.

No basis has thus been provided to conclude why one of skill in the art, at the time the application was filed, would have had a reasonable expectation of success in producing the claimed invention. Appellants respectfully submit that the necessary motivation and expectation of success are absent from the prior art. Reversal of the rejection under 35 U.S.C. §103 is therefore respectfully requested.

IX. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims are properly rejected under 35 U.S.C. §103. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: October 7, 2003

APPENDIX 1: APPEALED CLAIMS

10. A process for producing a fertile transgenic *Zea mays* plant comprising the steps of (i) bombarding intact regenerable *Zea mays* cells with DNA-coated microprojectiles; wherein said DNA comprises a preselected DNA sequence encoding a *Bacillus thuringiensis* endotoxin, wherein the preselected DNA sequence is adjusted to be more efficiently expressed in *Zea mays* than the native *B. thuringiensis* DNA sequence encoding said endotoxin; (ii) identifying a population of transformed cells comprising said preselected DNA sequence; and (iii) regenerating a fertile transgenic plant therefrom, wherein said DNA is expressed so as to impart insect resistance to said transgenic plant and is heritable.

11. The process of claim 10 wherein the preselected DNA sequence further comprises a selectable marker gene or a reporter gene.

12. The process of claim 10 or 11 wherein the fertile transgenic *Zea mays* plant is generated from transformed embryogenic tissue.

13. The process of claim 12 wherein the cells are derived from immature embryos.

14. The process of claim 10 or 11 further comprising obtaining transgenic insect resistant progeny plants of subsequent generations from said fertile transgenic plant.

15. The process of claim 14 further comprising obtaining seed from one of said progeny plants.

16. The process of claim 10 or 11 wherein the preselected DNA sequence comprises a sequence encoding the HD73 endotoxin of *Bacillus thuringiensis*.

17. The process of claim 10 or 11 wherein the preselected DNA sequence comprises a sequence encoding the HD1 endotoxin of *Bacillus thuringiensis*.

18. The process of claim 10 or 11 wherein the preselected DNA sequence comprises a sequence encoding the DH1 endotoxin of *Bacillus thuringiensis*.

19. The process of claim 10 or 11 wherein the preselected DNA sequence comprises a promoter.

20. The process of claim 19 wherein the preselected DNA sequence further comprises a promoter operably linked to said DNA sequence encoding said endotoxin and a promoter operably linked to said selectable marker gene.

21. The process of claim 11 wherein the selectable marker gene confers resistance or tolerance to a compound selected from the group consisting of hygromycin, sethoxydim, haloxyfop, glyphosate, methotrexate, imidazoline, sufolnylurea, triazolopyrimidine, s-

triazine, bromoxynil, phosphinothricin, kanamycin, G418, 2,2-dichloropropionic acid and neomycin.

22. The process of claim 21 wherein the compound is phosphinothricin.

23. The process of claim 11 wherein the compound is kanamycin.

24. The process of claim 11 wherein the compound is hygromycin.

25. The process of claim 10, 11, 16 or 17 wherein the DNA encoding said endotoxin comprises an increased number of maize preferred codons.

26. The process of claim 11 wherein the DNA encoding the *Bacillus thuringiensis*. endotoxin is fused in frame with said selectable marker or reporter gene.

27. The process of claim 18 wherein the truncated *Bacillus thuringiensis* endotoxin comprises about the N-terminal 50% of the endotoxin.

28. The process of claim 10 wherein the preselected DNA further comprises a protease inhibitor.

29. The process of claim 19 wherein the preselected DNA further comprises the maize AdhIS first intron or the maize *Shrunken-2* first intron positioned between the promoter and the DNA encoding said endotoxin.

30. The process of claim 19 wherein the preselected DNA sequence further comprises a manopine synthase promoter, a nopaline synthase promoter or an octopine synthase promoter.

31. The process of claim 19 wherein the promoter is the CaMV 35S or 19S promoter.

32. A population of plants obtained by breeding the transgenic plants of claim 10 wherein the preselected DNA sequence is transmitted by Mendelian inheritance through both male and female parent plants.